

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1 to 15 and 17 to 26 are currently pending. No claims are amended herein. Claims 16 and 27 to 66 have previously been cancelled.

Interview Summary.

Applicants appreciate the after final Interview granted with Examiner Mercier and Supervisor Gollamudi on May 15, 2007. The discussion mostly centered around written description and incorporation of negative limitations with regard to the claim 1 gels of cross linked proteins "not cross-linked with ... aldehydes".

Applicants noted that case law allows exclusion of positively recited limitations and finds adequate written description solely on the basis of examples existing in the specification wherein the provisoed out limitation is not employed in an embodiment. Applicant's representative noted that the present specification goes further in positively reciting aldehyde cross-linking, positively stating the undesirability of aldehyde cross linking, and providing multiple conceptual and past tense examples of the inventive gels not cross-linked with aldehydes.

Applicant requested a statement of facts to allegedly show that one skilled in the art would not believe the inventor possessed the concept of a gel not cross-linked with aldehydes at the time of filing. The Office raised the statement in paragraph 10 of the specification that "supplements can be protected ... by ... aldehyde cross-linking ..."

Applicants noted that this positive recital of the aldehyde alternate supports the negative limitation under the rule of *In re Johnson*. Applicants requested any further rejection (e.g., in an Advisory Action) by the Office along this line apply facts to law in explaining the rejection.

Further, with regard to claim 1, Applicants briefly noted that Perrier fails in the final Action as a section 103 reference because the Perrier methods produce free flowing membranous particles and does not teach a continuous phase matrix.

Applicants appreciated the useful suggestion from Supervisor Gollamudi that a Markush list of all alternate cross-linking chemistries could optionally avoid the aldehyde aspect in the claims.

35 U.S.C. §112, First Paragraph.

Claims 1-15 and 17-26 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants traverse.

In the rejection, the Action points to support offered in the previous Response for an amendment including the negative limitation wherein the cross-linked proteins are "not cross-linked with formaldehyde, glutaraldehyde or other aldehydes". However, the Action fails to state facts applied to law forming a basis for this rejection. The rejection is apparently based on the conclusory statement that the "exclusion ...[of aldehyde cross-linking] is new matter."

As cited in the previous Response, negative limitations are specifically provided for in MPEP 2173.05(i), *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977), and *Ex parte Parks*, 30 USPQ2d 1234, 1236 (1993). Applicants agree with the Examiner that to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the concept claimed in invention.

"If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims." See *In re Johnson*, *Id at 1019*. At paragraphs 8 and 10 of the specification, aldehyde cross-linking is positively recited as an undesirable alternative method of cross-linking proteins. Further, *In re Johnson*, held that a "specification having described the whole, necessarily described the part remaining." Here, the specification described the whole (cross-linking in general), the part removed (aldehyde cross-linking) and the part remaining (cross-linking without use of aldehydes), going far beyond the requirements of *In re Johnson*. The rejection must be withdrawn.

In *Ex parte Parks*, the inventor had claimed a reaction in the presence of a catalyst, while the specification also included examples of using high temperatures to drive the reaction without catalysts. The court found catalysis could be amended from the claim because it could not be said that the originally-filed disclosure would not have conveyed to

one having ordinary skill in the art that the inventors had possession of the concept of conducting the reaction without a catalyst. In *Parks*, written description was adequate where an embodiment in the specification did not include the excluded limitation. Here, the facts are quite similar. The originally-filed specification described the cross linking reactions with aldehydes and without. The specification describes cross linking generally and by a multitude of alternate or complimentary ways, including cross-linking with and without aldehydes (e.g., see Figure 1; claims 21, 31 and 61; and, paragraphs 8-10, 17, 59, 66, 69-70, 86 and 90). Controlling case law requires the rejections to be withdrawn.

The Action argues that it is unreasonable to conclude that the inventors had possession of the concept claimed invention at the time of filing. How can this be? The aspect of the claim at issue is, e.g., a continuous phase matrix of cross-linked proteins not cross-linked with formaldehyde. The original specification is replete with examples of continuous phase matrix of cross-linked proteins that were not cross-linked with formaldehyde. Although a positive recitation of aldehyde cross-linking is adequate support for exclusion by amendment (*In re Johnson*), here Applicants go further by openly disclosing aldehyde cross-linking and suggesting it is undesirable. Here, there are abundant examples of gels that were not cross-linked with aldehydes. Clearly, the concept of cross-linking without aldehydes was in possession of the inventors at the time of filing. The specification goes beyond the standard and it would be unreasonable to conclude that the inventors did not have possession of the claimed invention.

The facts applied to the case law, regulations and procedures clearly show the inventors had possession of the invention, as claimed. Applicants respectfully request withdrawal of the written description rejection.

35 U.S.C. §103(a).

Claims 1-15 and 17-26 were rejected under 35 U.S.C. §103(a) as allegedly obvious based on Perrier (U.S. 5,912,016) alone or in light of any number of secondary references. Applicants traverse.

Three requirements must be met for a *prima facie* case of obviousness. First, the prior art reference must teach all of the limitations of the claims. M.P.E.P § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to

produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. The teaching or suggestion to combine and the expectation of success must be both found in the prior art and not based on Applicants' disclosure. M.P.E.P. §2143. That is, a *prima facie* case of obviousness requires that the combination of the cited art, taken with the general knowledge in the field, must provide all of the elements of the claimed invention. When a rejection depends on a combination of prior art references, there must be some teaching, suggestion or motivation to combine the references. *In re Geiger*, 815 USPQ2d 1276, 1278 (Fed. Cir. 1987). Moreover, to support an obviousness rejection the cited references must additionally provide a reasonable expectation of success. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991), citing *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Perrier describes particles with proteinaceous outer surface walls interfacially cross-linked using hydrophobic acylating (R-C=O-) cross-linking agents.

Claim 1 is as follows:

A composite gel comprising:

a) a dispersed phase comprising lipid droplets or particles;

b) a continuous phase aqueous matrix comprising a pH ranging from about pH 4 to pH 9, and one or more cross-linked proteins not cross-linked with formaldehyde, glutaraldehyde or other aldehydes; and,

c) supplemental constituents;

wherein the dispersed phase is embedded within the continuous phase matrix; and, whereby supplemental constituents or lipid droplets, suitable for ruminant ingestion, are protected against degradation, modification, or removal from the gel during passage through a rumen.

Applicants note that the hydrophobic cross linkers of Perrier are only useful in forming membranous skins at an oil/water interface and do not participate in the formation of continuous phase aqueous matrices.

Perrier does not teach a continuous phase matrix of cross linked proteins. Perrier does not teach a dispersed phase embedded within a continuous matrix or an aqueous martix. The Action does not allege such teachings, so a case is not stated for the rejections based on Perrier.

Perrier alone does not render any of the claims obvious. Claims 1-8, 12-13, 15, 17-18 and 20-26 are rejected for alleged obviousness based on Perrier alone. As noted in the Action, Perrier discloses particles with walls of proteins cross linked on their surfaces.

Applicants note that the free flowing protein coated powder particles of Perrier do not describe a composite gel of independent claim 1. A composite gel refers to a continuous phase matrix of cross-linked proteins forming aqueous gel surrounding a dispersed phase of lipid droplets or particles. See paragraph 47 of the specification. The powder particles of Perrier are not a gel, particularly not an aqueous gel of cross-linked proteins in a continuous phase, nor has this been alleged. The particles of Perrier are not embedded in anything, particularly not a continuous aqueous phase matrix, nor is this alleged in the Action.

Because the Action fails to state a *prima facie* case, and review of Perrier shows it does not teach all limitations, the rejection of independent claim 1 for alleged obviousness must be withdrawn. Because dependent claims include all limitations of the claim upon which they depend, none of the dependent claims can be considered obvious in light of Perrier.

Further, with regard to claims 3 and 4, because Perrier does not describe a continuous phase or dispersed phase of a gel, Perrier can not teach supplemental constituents in these phases.

With regard to claim 12, although Perrier mentions oils, out of the context of the present claims, at column 8, line 40, this can not be considered to teach the specific fatty acids of the claim. Further, this is not properly alleged in the Action.

With regard to claim 13, the Action cites the mention of emulsions at column 3, line 39, as teaching emulsifiers. Applicants note that although emulsifiers can enhance, e.g., emulsification of oil in water, they do not have to be present to obtain an emulsion. Perrier does not teach emulsifiers and the Action does not actually allege such a teaching. Therefore, this rejection should be withdrawn.

With regard to claims 17 and 18, although Perrier mentions glucose out of context, this does not teach a continuous phase with a reducing sugar.

Claim 20 is directed to cross linking of the matrix proteins by heat.

Applicants can find no support for this rejection in the Action. Applicants note that Perrier chemically cross links his particle coat membranes with acyl group reactions. Because Perrier does not identify reaction temperatures, one of skill would assume the reactions occur at room temperature.

Claim 21 is directed to particular cross-linking mechanisms. The Action alleges only cross-linking with "acrylating [sic] polyfunctional crosslinking agents." This mechanism is not among those of the claim Markush group. A case is not stated and Perrier does not teach the limitation.

With regard to claims 22 to 26, Perrier does not teach a continuous phase matrix, so can not teach the parameters of the claims. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Here, the general conditions of the claim are not disclosed in the art, so it is inventive to discover the parameters. Moreover, a "particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." See, *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Here, no such result-effective variables are alleged in the action or known in the art with regard to the compositions of the present invention. Redundant reasons in law, fact and procedure exist for withdrawal of these rejections.

A reasonable motivation must be provided to modify a reference as suggested the Action. Here no modification is stated that would result in the compositions of the claim. Therefore, there has been no case stated, and there can not logically be a case stated. The Action at page 5 alleges motivation only for optimization of amounts to get maximum effect of the active ingredients. This motivation is irrelevant to most, if not all claims. The Perrier reference does not suggest a motivation for modifications away from his invention. Because a motivation is not presented, no *prima facie* case is stated.

Because no expectation of success in the modification is stated, again, there is no *prima facie* case. Of course, there can be no expectation of success because Perrier can

not be modified to provide the present invention. For example, the Perrier cross-linking agents can not form an aqueous gel.

Because there has been no case stated, not all limitations are taught, there is no motivation in the modification, and no expectation of success, Applicants respectfully request the rejections for obviousness based on Perrier be withdrawn.

Claims are not obvious based on Perrier in light of Richardson. Claims 9-10, 17-18 and 22-26 were rejected based on Perrier in light of Richardson (U.S. 5,143,737). Richardson teaches cross-linking proteins in a reaction with reducing sugars (Maillard reaction) that occurs at high dry temperatures to produce a dry brown cake (see Richardson at column 6, lines 18 and 42). Richardson does not teach a composite gel.

The primary reference, Perrier, does not teach several limitations of the claims, as discussed above. Because Richardson does not provide these limitations, the cited combination of references can not possibly teach the claims of the invention. For example, no combination of Perrier and Richardson can provide a composite gel or a continuous phase aqueous matrix. Therefore, the combination can not describe the independent claim or any dependent claim and the rejection must be withdrawn.

As discussed with reference to claims 20-26 above, the cited references do not teach a gel or continuous phase aqueous matrix, so can not teach the parameters of claims 9 10 or 22 to 26. The general conditions of the claims are not disclosed in the prior art, and the relevant parameters are not recognized as a result-effective variables, therefore, it is not obvious to discover the parameters, as discussed above. See, *In re Aller* and *In re Antonie*, *Id.*

Further, as was stated in the prior Response with regard to the same arguments (and not addressed in the current Action, as required by MPEP 707), the Action in the paragraph traversing pages 5 and 6 appears to imply that conjugated linoleic acid is inherent in Richardson because whey protein is used in the aqueous emulsions. However, as previously stated, whey protein does not necessarily include linoleic acid or conjugated linoleic acid. In fact the whey proteins and whey protein concentrates used in the references specifically do NOT include any milk fats (which are processed out of these commercially available products).

Assuming *arguendo* that the combination of references could provide all limitations of the claims (which they in fact do not), the combination would be unmotivated and therefore non-obvious. There is no suggestion in either cited reference to make the combination suggested in the Action. Further, the combination is unmotivated because the required modification of Perrier would have an unsatisfactory results. The Richardson baked cakes are apparently unsuitable for the use in cosmetics, etc., of Perrier. Therefore, the combination is further unmotivated, according to *In re Gordon*, 733 F.2d 900, 221 USPQ 1125. Further, it is suggested that the Perrier particles are at the edge of stability in suspension at 45°C, and would surely be damaged by the dry heat browning conditions of Richardson. Moreover, application of Richardson to Perrier would actually result in a product that is not a gel, as required in the present claims. The combination is further unobvious because the drying steps necessary to the browning in Richardson's technology teach away from the claimed invention. See, *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). Because the cited combination is not motivated, for a variety of reasons, it can not be considered obvious.

There would be no expectation of success because, as stated above, the Perrier particles are not stable at the browning temperatures of Richardson, Richardson does not actually teach the lipid components or the proper context, and in fact the combination would not succeed in providing the gel compositions of the present claims.

Because there has been no case stated, not all limitations are taught, there is no motivation in the modification, and no expectation of success, Applicant respectfully requests the rejections for obviousness based on Perrier in light of Richardson be withdrawn.

The Claims are not obvious based on Dollat in light of Perrier. The claims were rejected as allegedly obvious based on Dollat (U.S. 5,500,415) in light of Perrier. Dollat describes oil-in-water emulsions. Dollat teaches that the water can contain a protein that can be optionally be cross-linked using an aldehyde cross-linking agent. For example, Dollat teaches creation of a primary emulsion of oil in a melted protein solution (at a temperature above the gel point of the solution). Then, a secondary emulsion of spherules is formed of the first emulsion in an organic solvent. The spherules can be allowed to cool to an uncross-linked gel or optionally the spherules can be cross linking with aldehydes.

The combination of Dollat and Perrier does not teach all limitations of the claims, so can not render the claims obvious. For example, neither reference teaches a rumen protective composite gel that is not cross-linked with an aldehyde, as required by the claims. As discussed above, the membranous particles of Perrier can not be considered any kind of composite gel. As discussed below, the Dollat particles can not be considered rumen protective gels not cross linked with aldehydes.

The present rejection is based on the statement at page 8 that "[t]he process for making the emulsion is carried out at a temperature higher than the gel point, however, it is the examiners position that once the emulsion is allowed to cool, a gel would form." However, assuming this allegation were true, the Action still does not state a case. There is no allegation in the rejection that Dollat teaches a continuous phase matrix of cross-linked proteins not cross-linked with an aldehyde. In fact, the Action acknowledges that Dollat does not disclose cross-linking of proteins without aldehydes.

Further, should gels be formed on cooling of the protein solutions of Dollat, the gels without aldehyde cross linking would not be either cross-linked or rumen protective, as required by the claims. The Dollat gels in the discussion and examples are known to melt at about body temperature (e.g., gelatin melts at 35°C). Such gels are known to be degraded by the enzymes of a rumen and melted at rumen temperatures. The simple gels of Dollat are not protected against dissolution and degradation in the rumen of a ruminant animal. Dollat does not teach rumen protection and the uncross-linked gels would not be rumen protective.

The Action argues that it would have been obvious to substitute the cross-linking agents of Perrier in the processes of Dollat. However, careful reading of the cited references finds a teaching that would provide interfacial membranous cross-linking and not the continuous phase matrix gels of the present claims. It is clear the acylating polyfunctional cross linking agents of Perrier would not provide the gels of the present claims in combination with the processes of Dollat. The acylating polyfunctional cross linking agents of Perrier are hydrophobic molecules that are readily hydrolyzed and inactivated back to organic acids in the presence of water, thus they are stable and soluble only in the lipid phase and can only attack the outside surface of aqueous droplets at the oil/water interface to form walled structures, not gels. For example, at column 3, line 43,

Perrier describes processes wherein water-in-oil type emulsions of protein solutions are prepared in a hydrophobic (water immiscible) phase. Acylating polyfunctional cross linking agents are added to the hydrophobic phase resulting in formation of "membranes consisting of cross-linked molecules of the plant protein ... at the interface of the aqueous droplets." Perrier teaches that no gel is formed when using his cross-linker on a water-in-oil emulsion. The Dollat process is substantially identical to the Perrier process just described. To create the spherules of Dollat, the emulsion of oil in a protein solution was emulsified in a water immiscible solvent to prepare a water-in-oil secondary emulsion (see, e.g., abstract; column 2, line 38; and, column 3, line 56 to column 4, line 13). After the water-in-oil emulsion is established, Dollat adds the aldehyde cross-linking agent. However, the teaching of Perrier is that substitution of the acylating polyfunctional cross linking agents at this stage of the process would result in membrane formation and not a gel. Again, the combined teachings of the cited reference would not provide the rumen protected composite gels of the present invention.

Because the combination of Dollat and Perrier does not teach, e.g., rumen protective composite gels of a cross-linked protein continuous phase without aldehyde cross-linking, the combination can not render the claims obvious and the rejections must be withdrawn.

Assuming *arguendo* that the combination of references could provide all limitations of the claims (which they in fact do not), the combination would be unmotivated and therefore non-obvious. The Action fails to state a case for failure to suggest a motivation for the proposed combination. Even if a case were stated, there is no suggestion in either cited reference to make the combination suggested in the Action. Further, the combination is unmotivated because the required modification of Dollat would have an unsatisfactory result, as described above. For example, use of the Perrier acylating polyfunctional cross linking agents in the processes of Dollat would result in encapsulated emulsions different from those desired by Dollat, and not conforming to the present invention. Therefore, the combination is further unmotivated, according to *In re Gordon*, 733 F.2d 900, 221 USPQ 1125. Because the membranous particles of Perrier teach away from the gel spherules of Dollat, the combination is not obvious for teaching away from the claimed invention. See, *In re Geisler*,

116 F.3d 1465, 1471; 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). Because the suggested combination of references would require a substantial reconstruction and redesign of the elements shown in Dollat reference as well as a change in the basic principle under which the Dollat process was designed to operate, the combination is further not motivated, according to *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Because the cited combination is not motivated, for a large variety of reasons, it can not render the present claims obvious.

The Action has failed to provide facts supporting an allegation of an expectation of success in the proposed combination. In fact, there would be no expectation of success because the teachings of Perrier are directed to the production of membranous capsules and not gels, as discussed above.

Because the Action fails to state a *prima facie* case, and review of the cited combination of references shows they do not teach all limitations, the rejection of independent claim 1 for alleged obviousness must be withdrawn. Because dependent claims include all limitations of the claim upon which they depend, none of the dependent claims can be considered obvious based on Dollat in light of Perrier.

Dependent claim 4 is further non-obvious in light of the references because, e.g., neither reference has supplemental constituents in a continuous phase matrix.

With regard to dependent claims 22-26, the Action does not make specific allegations, but apparently bases the rejections on alleged general conditions described and on allegedly obvious optimization of "viscosity". As was discussed above with regard to rejections based on Perrier alone, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.", *In re Aller*, *Id.* Here, the general conditions of the claim are not disclosed in the art, so it is inventive to discover the parameters. Viscosity is not a general condition disclosed in the prior art. Further, the specific parameters of the claims were not optimized for viscosity, so such an optimization is irrelevant as a motivation. A "particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." See, *In re Antonie*, *Id.* Here, no

such result-effective variables are alleged in the action or known in the art with regard to the compositions of the present invention.

The Claims are not obvious based on Dollat or Perrier in light of Winowiski. The claims were rejected as allegedly obvious based on Dollat or Perrier in light of Winowiski (U.S. 4,957,748). Winowiski toasts grain meal in the presence of reducing sugars and notes a certain enhanced efficiency of protein utilization from the meal in ruminant animals.

Applicants note that proteins have been cooked with reducing sugars before the present invention, possibly resulting in reduced degradation of the proteins through the stomach of a ruminant. However, the context of Winowiski is such that there would be little motivation or expectation of success, in foresight, for the suggested combination. The dry roasting techniques of Winowiski are incompatible with the emulsions of Dollat or the membranous particles of Perrier. The dry baking and protein preservation techniques of Winowiski would change the principles of operation for both the other references. There would be no motivation or expectation of success because baking proteins for protection in rumens is unrelated to the goals stated for the products of Perrier and Dollat.

Unarguably, claim 19 is not obvious based on Perrier, Dollat and Winowiski because the combination fails to provide all limitations of claim 1, upon which claim 19 is dependent. Winowiski does not provide the limitations missing from the combination of Perrier and Dollat, as discussed above. For example, the combination does not provide a composite gel with a continuous phase aqueous matrix not cross-linked with an aldehyde.

Because no combination of any cited references teach all limitations of the claims, the rejections for alleged obviousness must be withdrawn. In addition, *prima facie* cases for the rejections have not been stated, the combinations are unmotivated, and there would be no expectation of success in the cited combinations of references. Therefore, several reasons exist showing the present claims are not obvious. Applicants respectfully request the rejections be withdrawn.

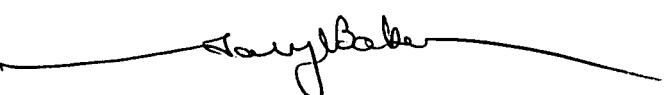
CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3510 to schedule an interview.

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Attachments:

- 1) A transmittal sheet; and,
- 2) A receipt indication postcard.